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| 10/560,605 | 03/23/2006 | Anil Kumar Tyagi | 11378.0066USWO | 9160 |
| 23552 | 7590 | 09/29/2010 | EXAMINER | |
| MERCHANT & GOULD PC | | | JOHANNSEN, DIANA B | |
| P.O. BOX 2903 | | | | |
| MINNEAPOLIS, MN 55402-0903 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/560,605 | TYAGI ET AL. | |
| | Examiner | Art Unit | |
| | Diana B. Johannsen | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 July 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4,9-11,13-16,18,21,22,24,26,27 and 29-31 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 1,2,11 and 29 is/are allowed.
 6) Claim(s) 3,4,13-16,18,21,22,24,26,27 and 30 is/are rejected.
 7) Claim(s) 9,10,18 and 31 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 13 July 2010 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>0810</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

FINAL ACTION

1. This action is responsive to the Amendment filed July 13, 2010. Claims 5-8, 12, 17, 19-20, 23, 25 and 28 have been canceled. Claims 1-4, 9-11, 13, 15, 18, 21-22, and 26-27 have been amended, and claims 29-31 have been added. Claims 1-4, 9-11, 13-16, 18, 21-22, 24, 26-27, and 29-31 are now under consideration. Applicant's amendments have overcome all rejections of and objections to claims 1-2, 11, and 29, and therefore claims 1-2, 11, and 29 are **allowed**. Claims 9-10, 18 and 31 are objected to for the reasons given below, and claims 3-4, 13-16, 18, 21-22, 24, 26-27 and 30 are rejected for the reasons given below. Applicant's arguments have been thoroughly reviewed and are addressed below. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Applicant's election with traverse of Group I in the reply filed on January 18, 2010 is again acknowledged. It is noted that all claims now pending are directed to the invention of Group I.

Claim Objections

4. Claim 18 remains objected to because of the following informalities: the claim recites "wherein step (b)" rather than "wherein in step (b)". Appropriate correction is required.

5. Claims 9-10 and 31 are objected to as being dependent upon a rejected base claim, but are directed to allowable subject matter (as indicated in the prior Office action).

Claim Rejections - 35 USC § 112, second paragraph

6. Claim 13-16, 18, 21-22, 24, 26, and 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-16, 18, 21-22, 24, and 26 remain indefinite over the recitation of the limitation “the primary recombinant mycobacterium strain of step (i)” in step (j) of claim 13. Step (i) does not in fact recite a single strain but rather multiple “strains”. It is therefore not clear whether step (j) requires the multiple strains of step (i), or whether it embraces, e.g., any individual strain selected from those strains (or a particular such strain). Accordingly, the metes and bounds of the claims are not clear. Dependent claim 26 remains additionally unclear for the same reasons as the claims reference a single individual strain when the independent claim recites multiple “strains”.

Applicant’s traversal stating that “step (j) refers to any individual strain selected from those strains that show resistance to antibiotic hygromycin” is noted; however, the language of the claim itself appears to require a specific particular strain (by referencing “the....strain”, as compared to step I, which references culturing “the...strains” of the prior step). It is noted that, in view of applicant’s comments, this rejection could be overcome by simply amending step (j) to reference either “the....strains” or “a....strain” (rather than “the....strain”). Claim 26 could be similarly amended to overcome the

rejection.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS' AMENDMENTS:**

New claim 30 is indefinite over the recitation of a recombinant vector "consisting of SEQ ID NO: 15." As SEQ ID NO: 15 is identified in the specification as a "modified mptpA" gene, it is unclear how a molecule "consisting of" this sequence could be considered a vector (further, no such vector was disclosed, as indicated in the rejection under 35 USC 112, first paragraph set forth below). Thus, it is unclear what construct is being claimed in new claim 30.

Claim Rejections - 35 USC § 112, first paragraph

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS' AMENDMENTS:**

7. Claims 27 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claim 27 as amended is drawn to a "primer comprising SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, or SEQ ID NO: 4". The originally filed specification does not provide basis for such primers. Rather, the originally filed specification discloses primers "selected from a group comprising of SEQ ID NO: 1 to 4 for amplification of *mptpA* along with its flanking regions" (see text of original claim 24, as well as page 11

of the specification), and exemplifies the use of primers consisting of SEQ ID NOs 1-4 (see, e.g., Table 1 at page 21 and the Examples). There is no disclosure in the specification of the broad genus of primers set forth in claim 27 as amended. Claim 30 as amended requires a recombinant vector “consisting of SEQ ID NO: 15”. No such vector is disclosed in the originally filed specification (rather, SEQ ID NO: 15 is disclosed as being a modified *mptpA* gene, and vectors comprising this sequence/gene are disclosed in the specification). Accordingly, applicant’s amendments add new matter to the claims.

8. Claims 3-4, 13 and 22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons given in the prior Office action of April 13, 2010.). **It is again noted that this rejection can be overcome by providing a deposit for patent purposes of vector "pAKΔA".**

The response traverses the rejection on the following grounds. The response urges that the claims are enabled without a deposit of the claimed vector. The response references the “detailed description of the steps involved in the production of” the vector at page 12, stating that this section of the specification “discloses all the details including the site and steps involved in the construction of this vector,” and noting that “the respective sequences are mentioned in Table 1 of the description”. This argument has been thoroughly considered but is not persuasive. As was noted in the

rejection, the guidance at pages 12-13 with regard to construction of pAKΔA is quite detailed, and the examiner concurs that these instructions could be employed to prepare a construct very similar in structure to the claimed vector. However, the guidance in the specification would not allow one to envision the precise construct being claimed, as is apparent upon a thorough reading of the description at pages 12-13 (for example, the method of end repair employed at several points would affect the precise sequence of pAKΔA, and it is therefore not known what sequences would be present at these junctions). Accordingly, this rejection is maintained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634